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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,890	KOSZINOWSKI ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-44,46-48,50,51,53,54,56-64 and 67-72* is/are rejected.

7)☒ Claim(s) *45,49,52,55,65 and 66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of an amendment, filed on 4/29/2002, in which several claims were amended (claims 36, 45-46, 48-50, 57, 67-70 & 72). The amendment has been entered in part, with the proposed amendment of claim 68 not being entered. The clean version of the proposed amendment does not match the previous copy of the claim or the marked-up version submitted on 4/29/2002 (i.e. with regard to the phrase "contained in the bacterial cell"). Claim 68 has been examined according to the previous version of the claim (see the preliminary amendment filed 1/31/2000). Applicants are required to clarify in any subsequent response to this action what is intended for claim 68. Applicants are reminded of the revised guidelines for amendment practice (see http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf).

Claims 36-72 are pending and under consideration in the instant application. Any rejection of record in the previous office action, mailed on 10/2/2001, not addressed herein is withdrawn. This action is not final as there are new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims in the response of 4/29/2002.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The priority document is a German application that is printed in German (DE 197 33 364.8, filed on 1 August 1997). The examiner has identified a U.S. patent (U.S. Pat. No. 6,277,621 B1 filed on 26 February 1998) that antedates the international filing date of the instant application (31 July 1998), yet was filed in the U.S. after

the filing date of the German application. Rejections for several of the pending claims based upon the intervening U.S. patent follow. In addition, rejections for several of the claims under 35 U.S.C. 102(a) over the teachings of Messerle et al and Delecluse et al are made below. Applicant cannot rely upon the foreign priority papers to overcome these grounds of rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. See also 37 CFR 1.55(b)(4). In order to obtain benefit of the filing date of the foreign application, applicants must submit a certified translation of the priority document.

Sequence Compliance

Receipt is acknowledged of a supplemental sequence listing filed on 7/25/2001. This submission does not place the instant application into sequence compliance for at least three reasons. First, there is no clear statement from applicants' representative concerning New Matter in the submitted sequence listing and CRF. Second, the sequences provided for SEQ ID NOS: 1 & 3 do not match any of the sequences present in Figure 23. It appears that what has happened is that the reverse sequences for the top and third sequences in the figure have been presented as SEQ ID NOS: 1 & 3. These are not, however, the actual sequences presented in the figure as the sequences in the figures do have a 5'-3' directionality from left to right in the figure. Finally, neither the figure nor the Brief Description of the Drawings has been amended to include the appropriate sequence identifiers.

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be

considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Drawings

The replacement drawings were received on 8/22/2002. These drawings are accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-44, 63-64 & 71-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is vague and indefinite in that the metes and bounds of the phrase "derived from" are unclear. **This is a new rejection.** It is unclear the nature and number of steps required in order to produce a "derivative" of a DNA virus. It would be remedial to amend the claim language to "obtained from", which implies a more direct process for producing the infectious viral genomic sequence.

Claims 63-64 are vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "said cloning vehicle sequence" in claim 57, upon which these claims are dependent. **This is a new rejection necessitated by applicants' amendment of the claims in the response filed on 4/29/2002.**

Claim 68 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "the DNA molecules" in claim 67, upon which claim 68 is dependent, due to the fact that there are multiple DNAs recited in claim 67 (e.g. mutagenizing DNAs and the recombinant vector of claim 36). It appears that the limitation is meant to refer to the "mutagenizing" DNA molecules of claim 67 and it would be remedial to amend claim 68 accordingly. **This is a new rejection that is necessitated by applicants' amendment of the claims in the response filed on 4/29/2002.**

Claim 71 is vague and indefinite in that the metes and bounds of the phrase "obtained in accordance with the method of claim 67" are not clear. **This is a new rejection.** The concept of what constitutes a method "in accordance with" the method recited in claim 67 is not explicitly defined in the instant specification. For example, it is not clear that the cited phrase means that each of the methods steps of claim 67 need necessarily be followed in the production of the recombinant vector. Nor is it clear, due to the cited phrase and the fact that claim 67 uses open claim language, what are the structural/functional characteristics of the resulting recombinant vector (e.g. see the prior art rejections against claims 71 & 72 that follow). It would be remedial with regard to 35 U.S.C. 112 2nd paragraph to amend the claim language to explicitly state that the recombinant vector is "obtained by" the method of claim 67.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-43, 46-48, 50-51, 53-54, 56-64 & 67-72 are rejected under 35 U.S.C. 102(a) as being anticipated by Messerle et al (PNAS USA, December 1997, Vol. 9, pages 14759-14763; see the entire reference). **This is a new rejection. As indicated above, the instant rejection is made in light of the fact that the claim for foreign priority to the German 197 33 364.8 application has not yet been perfected. In order to perfect the claim for priority under 35 U.S.C. 119, applicants will need to submit a certified translation of the priority document.**

Messerle et al is a non-patent literature publication by several of the inventors of the instant application that describes many of the experiments taught in the instant specification.

Messerle et al teach a strategy for cloning and mutagenesis of an infectious herpesvirus genome as part of a BAC plasmid (e.g. Abstract; Figure 1). The exemplified embodiment features the construction of BAC/MCMV constructs that comprise all of the elements required for replication and packaging of infectious murine cytomegalovirus (MCMV) (e.g. Abstract; Figure 1; page 14760, column 2 "Generation of Recombinant Viruses and BAC Plasmids"). In particular, Messerle et al teach the use of homologous recombination to generate a mutagenized BAC/MCMV construct where the viral genome has been mutagenized in the immediate-early region (i.e. ie1) (e.g. page 14761, "Construction of a MCMV ie1 Mutant by Homologous Recombination in *E. coli*"). The constructs taught by Messerle comprise LoxP sites flanking the BAC/selectable marker sequences inserted into the MCMV genome (e.g. Figure 2 legend).

Messerle et al further teach that mutagenesis of the viral portion of BAC/CMV constructs can be done *in vivo* using transposon mutagenesis (e.g. page 14762, columns 1-2, bridging paragraph).

Claims 36, 38-39, 48, 51, 54, 57-60, 63-64, 67-69 & 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent). **This is a new rejection. As indicated above, the instant rejection is made in light of the fact that the claim for foreign priority to the German 197 33 364.8 application has not yet been perfected. In order to perfect the claim for priority under 35 U.S.C. 119, applicants will need to submit a certified translation of the priority document.**

Horsburgh et al (the '621 patent) teach the construction and use of artificial chromosome constructs containing foreign nucleic acid sequences, such as viral nucleic acid sequences, that are useful for therapy and recombinant virus production (e.g. Abstract). Horsburgh et al teach embodiments using bacterial artificial chromosomes (i.e. BACs) that comprise a nucleic acid sequence that directs formation of a recombinant virus (e.g. herpesvirus) upon introduction into a cell (e.g. claims 1 & 5; columns 11-12). The '621 patent contemplates numerous different viral genomes for use in producing the BAC/viral genome constructs of their invention, including: herpesviradae such as HSV-1, HSV-2, VZV, CMV, EBV, HHV6 or HHV7 (e.g. column 3, lines 42-62). In particular, the '621 patent teaches the construction of a vector (HSV-BAC-TK) that comprises a BAC sequence (BAC-TK) operatively fused to the entire HSV-1 genome (e.g. column 11, lines 17-29). HSV-BAC-TK was constructed via the co-transfection of Vero cells with a linearized plasmid (BAC-TK, comprising a BAC vector and HSV tk sequences flanking a

chloramphenicol resistance gene, CAT) such that virus was produced comprising the BAC sequences inserted into the tk locus. Vero cells were subsequently infected with HSV-BAC-TK and circular forms of the genomic DNA isolated. The isolated circular forms, comprising the BAC/CAT sequences, were then electroporated into *E. coli* and recombinant colonies screened for resistance to chloramphenicol. Isolated clones were then analyzed by PCR and restriction enzyme analysis, and it was confirmed that the entire HSV genome had been cloned into the BAC vector. Transfection of these clones back into eukaryotic cells resulted in the production of viral plaques. Virus from these plaques were isolated, amplified and analyzed to confirm that the HSV-BAC-TK clones comprised the same genomic restriction patterns as the parental genomes and that the passaged virus performed similarly in one-step growth experiments to the parental strains (e.g. column 11, lines 30-55). Horsburgh et al teach that it is desirable, if one wants to generate a BAC/viral genome construct that is capable of producing replicable virus in appropriate host cells, to insert heterologous sequences into nonessential regions of the viral genome (e.g. column 6, lines 40-60).

The '621 patent teaches an example where an HSV-BAC genome is mutagenized by introducing the HSV-BAC genomic DNA into a bacterial cell comprising a mutagenizing nucleic acid (p53-lacI-kan-UL55) and subsequent selection of recombinants that comprise an interrupted UL54 sequence based upon their ability to grow on kanamycin, IPTG and chloramphenicol plates (e.g. columns 12-13, bridging paragraphs).

Claims 36, 38-39, 43, 48, 51, 54, 57-60 & 63 are rejected under 35 U.S.C. 102(a) as being anticipated by Delecluse et al (Proceedings of the National Academy of Sciences, USA. 7 July 1998, Vol. 95, pages 8245-8250; see the entire reference). **This is a new rejection.**

Delecluse et al teach the design and utilization of a system that allows the cloning of any γ-herpesvirus in *E. coli* onto an F factor-derived plasmid (e.g. Abstract). Delecluse et al exemplify their method utilizing the complete genome of a strain of Epstein-Barr Virus, B95.8. Using homologous recombination in a human lymphoblastoid cell line (i.e. B95.8) that comprises the viral genome, Delecluse et al inserted a prokaryote-derived cassette comprising sequences encoding hygromycin resistance and green fluorescent protein (GFP) as well as the F factor sequences required for replication in *E. coli* (e.g. Figure 1; page 8247, column 1, "Cloning of the B95.8 EBV DNA in *E. coli*"). Circular EBV genomic DNAs were obtained from the B95.8 cells and subsequently electroporated into *E. coli* DH10B cells (e.g. Figure 1; page 8247, column 1, "Cloning of the B95.8 EBV DNA in *E. coli*"). Three independent clones were obtained from B95.8 cell lines shown to have incorporated the F factor cassette into B95.8 and were used to establish 293 cell clones that produce infectious virions (e.g. page 8247, columns 1-2, bridging paragraph; Figure 4; page 8248, column 1, "Discussion").

Claims 71-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference). **This is a new rejection.**

Messerle et al teach the construction of two BAC/MCMV hybrids wherein the hybrid vectors comprise BAC sequences and an infectious viral genomic sequence of >200kb (i.e. 235

kb minus ~15 kb), where the hybrid vectors can be replicated in *E. coli* and where the vectors can be used in mammalian cells to produce MCMV virions (i.e. due to complementation between the two vectors upon co-transformation in eukaryotic host cells).

As indicated above, claim 71 is vague and indefinite in that the metes and bounds of the phrase "obtained in accordance with the method of claim 67" are not clear. The concept of what constitutes a method "in accordance with" the method recited in claim 67 is not explicitly defined in the instant specification. For example, it is not clear that the cited phrase means that each of the methods steps of claim 67 need necessarily be followed in the production of the recombinant vector. Nor is it clear what are the structural/functional characteristics of the resulting recombinant vector due to the cited phrase and the fact that claim 67 uses open claim language. Thus, claim 71 can reasonably be interpreted broadly to encompass any BAC vector that comprises any mutated sequence from a virus having a genome of greater than 100 kb and which could be obtained by the claimed method (e.g. the BAC/CMV constructs taught by Messerle et al). As currently written, the rejected claims do not specify any structural/functional characteristic that is necessarily conveyed to the claimed recombinant vector by the method of mutagenesis recited in claim 67. It may be remedial to amend claim 71 to include such structural/functional limitations.

Claims 36, 38, 48, 51, 54, 57-59, 63, 67 & 70-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Luckow et al (Journal of Virology, 1993, Vol. 67, No. 8, pages 4566-4579; see the entire reference). **This is a new rejection.**

Luckow et al teach the construction and use of bacmid vectors (i.e. baculoviral shuttle vectors) that comprise an infectious genome sequence obtained from the baculoviral strain AcNPV (~130 kb) operatively fused to a mini-F replicon that allows autonomous replication and stable segregation of plasmids at low copy number in *E. coli*. The bacmid vectors further comprise a selectable kanamycin resistance marker and attTn7 sites that allow transposon-mediated insertion of heterologous nucleic acid sequences into the bacmid vector (e.g. Abstract; page 4567, columns 1-2, bridging paragraph; Figure 1). The method for constructing the bacmid vectors is schematically shown in Figure 1. The cassette comprising the prokaryotic replication sequence, selection sequence and attTn7 sites was co-transfected into insect cells with an infectious AcNPV genome and homologous recombination allowed to occur between the viral genome and the baculoviral sequences flanking the cassette. Viruses comprising the recombinant bacmid genome were then isolated. The isolated recombinant bacmid DNA was then transfected into *E. coli* for maintenance and further manipulation (e.g. Figure 1; pages 4570-4571, bridging paragraphs). Bacmid DNA isolated following amplification in *E. coli* was capable of infecting insect cells to produce baculovirus comprising the recombinant bacmid DNA (e.g. Figure 1; page 4567, column 1, last paragraph; pages 4572-4573, bridging paragraphs). Luckow et al further teach transposon-mediated mutagenesis at the attTn7 sites of different bacmid vectors in *E. coli* to generate new bacmid vectors comprising a heterologous sequence encoding a desired polypeptide (e.g. *B*-glucuronidase). Virions comprising the recombinant bacmids were subsequently introduced into insect cells for expression of the desired protein (e.g. Figures 1, 5 and 6; page 4574, column 2 & page 4576, column 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37, 40-43 & 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) in view of Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference). **This is a new rejection.**

The teachings of Horsburgh et al (i.e. '621 patent) and of Messerle et al are outlined above and are applied here as before, except:

Horsburgh et al do not reduce to practice their invention for generating and mutagenizing BAC/viral genome vectors with a viral genome greater than 200 kb in length.

Messerle et al do not reduce to practice the construction of a BAC/MCMV vector comprising all of the MCMV sequences required to replicate and package the recombinant vector.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the invention taught in the '621 patent with a complete cytomegaloviral genome because Horsburgh et al teach it is within the skill of the art to construct and mutagenize a BAC/whole viral genome construct using a mammalian virus comprising a very large DNA genome and because Messerle et al teach it is within the skill of the art to construct and use a BAC/MCMV vector comprising nearly all of the sequences required to replicate and package the vector as a viral genome (i.e. BACS comprising ~220 kb of the ~235 kb MCMV genome). One would have been motivated to do so in order to receive the expected benefit, as taught by Horsburgh et al, of being able to take advantage of the great power of bacterial genetics to produce and maintain different BAC/CMV constructs in bacteria which are also capable of productive infection once transfected into appropriate eukaryotic host cells. Absent any evidence to the contrary, there would have been a reasonable expectation of success in using the combined teachings of the two references to obtain BAC/CMV constructs comprising greater than 200 kb of DNA and which comprise all of the viral sequences required for replication and packaging into CMV virions.

Examiner's Note

In addition to the references cited above, other references are cited on the attached PTO-892. These additional other references do not anticipate or make obvious the invention of the

pending claims, but are relevant with regard to the art of constructing BAC vectors comprising an infectious viral genome sequence of greater than 100 kb.

Conclusion

Claims 36-72 are pending in the instant application, with claims 36-44, 46-48, 50-51, 53-54, 56-64 & 67-72 rejected herein. Pending claims 45, 49, 52, 55 & 65-66 are objected to as being dependent upon rejected claims, but would be allowable if amended to include each of the limitations of the rejected claims upon which they are currently dependent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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